

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2 Sheets
-------	---	----	----------

Complete if Known

Application Number	10/551,396
Filing Date	03/31/2004
First Named Inventor	Meikle, et al.
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	MAYO-0008 US1 (128675.00044)

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
/GC/	5	WO 97/44668	11-27-1997	Meikle, et al.	Entire Application	
/GC/	6	WO 00/55632	09-21-2000	Meikle, et al.	Entire Application	
/GC/	7	WO 03/106997	12-24-2003	Meikle, et al.	Entire Application	

Examiner Signature	/Gary Counts/	Date Considered	11/30/2009
-----------------------	---------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313.**

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2 Sheets

Complete if Known

Application Number	10/551,396
Filing Date	03/31/2004
First Named Inventor	Hopwood, et al.
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	MAYO-0008 US1 (128675.00044)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/GC/	8	CHANG M.H.Y. et al. Saposins A, B, C and D in Plasma of Patents with Lysosomal Storage Disorders. Clinical Chemistry 43: 8 1325 (2000).	
/GC/	9	MEIKLE, P.J., et al. Diagnosis of Lysosomal Storage Disorders: Evaluation of Lysosome-Associated Membrane Protein LAMP-I as a Diagnostic Marker. Clinical Chemistry 43: 8 1325-1335 (1997).	
/GC/	10	Meikle PJ, Ranieri E, Ravenscroft EM, Hua CT, Brooks DA, Hopwood JJ. Newborn screening for lysosomal storage disorders. Southeast Asian J Trop Med Public Health. 1999;30 Suppl 2:104-10.	
/GC/	11	RENLUND, et al. Studies on the Defect Underlying the Lysosomal Storage of Sialic Acid in Salla Disease. The Journal of Clinical Investigation. 77(2):568-74 (Feb. 1986).	
/GC/	12	UMAPATHYSIVAM, K., J.J. HOPWOOD, P.J. MEIKLE. Determination of acid alpha-glucosidase activity in blood spots as a diagnosis for Pompe Disease, Clin. Chem. 47(8): 1378-1383 (2001).	
/GC/	13	UMAPATHYSIVAM, K., J.J. HOPWOOD, P.J. MEIKLE, Determination of acid alpha-glucosidase activity Protein: Evaluation as a Screening Marker for Pompe Disease and Other Lysosomal Storage Disorders. Clin. Chem. 46:9 1318-1325 (2000).	
/GC/	14	WHITFIELD PD, Nelson P, Sharp PC, Bindloss CA, Dean C, Ravenscroft M, Fong BA, Fietz MJ, Hopwood JJ, Meikle PJ. Correlation among genotype, phenotype, and biochemical markers in Gaucher disease: implications for the prediction of disease severity. Mol Genet Metab. 2002 Jan;75(1):46-55.	

Examiner
Signature

/Gary Counts/

Date
Considered

11/30/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313.